

REMARKS

Claims 1-22 are pending in this application.

Double Patenting rejection

The rejection of claims 1-22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,649,174 is maintained, since allegedly, although the conflicting claims are not identical, they are not patentably distinct from each other because the instant independent claims encompass the patent claim regarding the film forming agent and ratio. To obviate this rejection, the Applicants are directed to submit a terminal disclaimer in compliance with 37 CFR 1.321(c), as the conflicting patent is commonly owned with the present application. The Examiner has noted that "Applicants stipulate that the rejection remains in effect until such time as they amend or file a TD".

Rejections under 35 U.S.C. 103(a)

(1) Touzan *et al.* and Shah *et al.*

Claims 1, 2, 4-9, and 11-19 are rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over Touzan et al. (hereinafter "the '496 reference") in view of Shah et al. (hereinafter "the '155 reference"). The rejection, repeated from the office action of November 16, 2006, states in relevant part:

Touzan et al teach a two phase composition for cleansing containing a demixing agent (title, abstract). An aqueous and separate oily phase in a ratio of 30:70-60:40 is disclosed (abstract). Isohexadecane, liquid paraffins, and silicone oils including cyclopentadimethylsiloxane are disclosed (column 4 lines 1-20). Colorants are specified (column 4 line 25).

Shah et al teach a polyvinylpyrrolidone/vinyl acetate copolymer at 1-5% to maintain pigments in suspension (column 4 lines 37-57). Applicants disclose this polymer on page 2 line 33.

It would have been obvious to one of ordinary skill to add a polyvinylpyrrolidone/vinyl acetate copolymer to the composition of Touzan et al for the beneficial effect of maintaining colorants in suspension in view of Shah et al."

Applicants argue that one of ordinary skill would not add PVP to the composition of Touzan et al as a suspension agent because only a mere 0.05% colorant is disclosed, compared to the large amounts of colorant in Shah et al. The implication is that

PVP is only effective for large amounts of colorant. However, this is mere speculation. Applicant also argue that demixing compositions are difficult to make, therefore, one of ordinary skill would not add PVP, a known suspension and emulsion stabilizer, because it would interfere with the demixing function. However, Touzan et al already use emulsifying agents, namely the many surfactants cited at column 2 line 36 et seq. that is, one of ordinary skill, reading that Touzan et al, is already using such agents, it argue, would be motivated to accommodate the addition of another, such as PVP.

This rejection again, is respectfully traversed. Prior to addressing the merits of the office action, the Applicants wish again to restate the nature of the present invention. The present invention is directed to a dual phase liquid cosmetic composition comprising an oily phase and an aqueous phase in a ratio of 30:70 to 70:30, and a demixing agent. The phases are separate from one another before and after being mixed at the time of use. The dual phase composition prepared with a film former as the demixing agent emulsifies rapidly and uniformly upon vigorous shaking and demulsifies completely upon resting for a few minutes. That a film former could be used as a demixing agent to facilitate rapid separation of phases in a two phase emulsion is considered both surprising and unexpected.

The '496 reference

The '496 reference describes a dual phase cleansing composition having an aqueous phase and an oily phase. The aqueous phase contains, as a demixing agent, a specific class of surfactant, the alkyl dimethylbenzylammonium ("benzalkonium") chlorides. The reference does not disclose or suggest the presence of a film former, nor the use of film formers as demixing agents. The Examiner relies on the disclosure of film formers in the '155 reference in an attempt to establish *prima facie* obviousness of the present invention.

The '155 reference

The reference discloses a dual phase composition, and is principally directed to cosmetic compositions emphasizing color. The two phases are both aqueous and therefore miscible. One of the aqueous phases is a gel phase, while the other phase is a color phase. The color phase is manipulated and disposed in a container against a background of the gel phase such that the color phase appears completely engulfed in the gel. The two phases are kept separated before use to provide an aesthetically attractive product in which the color phase does not bleed into the gel phase, and in which the product highlights the critical color emphasis of the composition. The phases are only mixed at the time of use to form a homogenous composition, and, once mixed, the two phases are never demixed. As further taught in the reference, each phase may contain PVP. The gel phase, as taught at column 5, lines 55-65,

includes a water soluble resin as a thickener, which may be PVP. The color phase contains a protective colloid which acts like an emulsifier by coating the surfaces of pigment particles in the dispersed phase, thus preventing coalescence and subsequent separation, and keeping the pigment particles from bleeding into the gel phase. PVP and PVP/VA copolymer may be used for this purpose.

Combined teachings of the '496 and the '155 references

Under a correct analysis for obviousness, the question is whether the proposed combination (modified product), based on the disclosure in the references, would have been obvious to a person of ordinary skill in the art; for example, whether there was any need or problem in the cosmetic field at the time of the invention addressed by the references which could provide any reason for combining the elements in the manner claimed. It is the Examiner's assertion that one of ordinary skill in the art would have been motivated to modify the dual phase compositions of the '155 reference, by the addition of PVP/VA copolymer, for the purpose of maintaining a substantial amount of colorant in suspension, as taught in the '496 reference, and thus arrive at the present invention.

The '155 reference teaches that the PVP/VA copolymer as protective colloid would be needed to disperse 1 to 60 weight percent pigment (based on the total weight of the color phase composition) to prevent precipitation of the colorants, and to keep the pigment from bleeding into the gel phase. Further, as the Applicants noted in response to the previous office action, in all of the many examples in the reference 30 to 40 weight percent pigment is employed. The reference thus teaches that the PVP/VA copolymer would only be required to suspend a substantial amount of pigment in an aqueous phase, and suggests that the protective colloid would not be needed for relatively small amounts of pigment, such as that amount, 0.05% pigment, disclosed in a single example in the '496 reference. Therefore, unless a substantial amount of pigment (i.e. at least 1%, and typically, 30-40%) were being introduced into the dual phase composition of the '496 reference, the '155 reference suggests that introduction of a protective colloid, e.g. PVP/VA copolymer would not be indicated. Thus, the Applicants are not implying, in contrast to the statement of the Examiner, that the protective colloid would not be effective to disperse small amounts of colorant, but merely that the '155 reference teaches or suggests that the protective colloid is not indicated for suspending small amounts of colorants.

Nevertheless, it is the Examiner's position that, in the event that one skilled in the art did wish to add a relatively large amount of colorant and PVP/VA copolymer to the cleansing compositions of the '496 reference, one skilled in the art could reasonably predict that this could

be done successfully without negatively affecting the properties of the '496 dual phase compositions.

However, such a statement by the Examiner is a mere unsupported conclusion. There is no disclosure or suggestion in the references that the proposed modification (i.e. introducing a substantial amount of pigment into the dual phase composition) would be desirable, nor that such addition would solve any longstanding problem in the cosmetic arts. Moreover, introducing a further stabilizing/dispersing agent (e.g. PVP/VP copolymer) into the dual phase compositions in the '496 reference is counterintuitive; that is, if one having ordinary skill in the art of dual phase cosmetic formulation had any prediction whatsoever about the efficacy of the modified composition, it would be that the additional stabilizing ingredients would negatively affect the properties of the '496 composition, in particular, the demixing capability of the composition. The '155 reference, in teaching the use of PVP/VA copolymer to suspend pigments, teaches away from the achievement of the present invention wherein the film former performs a demixing function. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the claimed invention. *In re Gurley*, 31 USPQ2d 1130, 1131 (CAFC 1994).

Additionally, as discussed in the introductory paragraphs of the '496 reference (and in the introductory paragraphs of cited U.S. Patent No. 5,871,758 to Nagy et al), the prior teaches against the random mixing of ingredients in formulating a successful, that is, properly functioning, two phase composition, and in particular, a two phase composition which emulsifies readily on shaking but whose constituents segregate rapidly on standing. A number of factors must be considered. At the very least, such compositions call for a certain balance of surfactants/emulsifiers and demixing agents to achieve the desired result. Therefore, in contrast to the position of the Examiner that, "...as the '496 reference already uses emulsifying agent, namely the many surfactants...one of ordinary skill, reading that Touzan *et al*, is already using such agents, would be motivated to accommodate the addition of another, such as PVP.", the Applicants assert that it also would be considered counterintuitive by those skilled in the art of cosmetic formulation to merely throw into the dual phase composition of the '496 reference another stabilizing agent, e.g. a surfactant, an emulsifier, a dispersant, etc., with any reasonable expectation that such additional ingredients would not adversely affect at least the demixing capability of the product by further stabilizing the two phase emulsion.

Furthermore, one skilled in the art of cosmetic formulation could not easily predict the effect that the addition of a substantial amount of pigment, would have on the providing a successful dual phase composition.

For all of the above reasons, it is considered that the Examiner has not established a *prima facie* case of obviousness, and that independent claims 1 and 8 are patentable over the references cited. Dependent claims 2, 3; and 9 and 10, which depend respectively from the independent claims, are particularly preferred embodiments of the invention which recite preferred film formers for use in the invention. Dependent claims 5 and 12 describe further embodiments of the invention which specify a desired amount of the film former in the dual phase compositions. Dependent claim 7 recites a preferred ratio of the oil and aqueous phases. Dependent claim 13 calls for a preferred combination of oils in the oily phase of the composition.

It is respectfully submitted that the rejection of the claims under §103(a) in view of the combined teachings in the '496 and the '155 references must be withdrawn.

(2) Grollier *et al.* and Nagy *et al.*

Claims 1, 2, 4-8 and 10-22 also stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nagy *et al* (hereinafter "the '758 reference") in view of Grollier *et al* (hereinafter "the '095 reference"). The rejection which is restated from the official action of November 16, 2006, states in relevant part:

Nagy *et al* teach a makeup removing composition comprising two phases and a demixing agent (abstract). A 30:70-70:30 ratio of oil to aqueous phase is disclosed (column 3, lines 12-14). Mixtures of cyclic silicones, dimethicone and a volatile C16 paraffin are specified (column 4, lines 33-53).

Grollier *et al* teach two phase compositions comprising a cationic polymer for skin conditioning (abstract). Vinyl pyrrolidone-acrylamide copolymers are specified at 0.2-50% (column 8, lines 1-26, column 9, lines 20-24). Dimethylaminoethylmethacrylate is disclosed (column 8 line 59). Applicants disclose PVP/dimethylamino ethylmethacrylate on page 2 line 32. It would have been obvious to one of ordinary skill to add a vinylpyrrolidone-acrylamide copolymer to the composition of Nagy *et al* to achieve the beneficial effect of a skin conditioner in view of Grollier *et al*.

Applicants make the same argument here as in their response to the first 103, regarding the difficulty of making demixing compositions. However, here, Nagy *et al* teach hair conditioners (column 4 line 9). The cited Grollier *et al* polymers are such compounds. Thus, it is argued, one of ordinary skill, reading Nagy *et al*, would be motivated to accommodate the addition of the Grollier *et al* polymers. Applicants also argue that Nagy *et al* teach demixing agents in the aqueous phase. However, the motivation to combine concerns a skin conditioning agent, not a demixing agent. Applicants also argue that Grollier *et al* teach

against addition to the oil phase. However, Grollier et al is referring to anhydrous compositions.

This rejection is again respectfully traversed.

The '758 reference

The '758 reference addresses the problems encountered in the art in attempting to formulate a liquid dual phase cleansing composition comprising an oil phase and an aqueous phase, and, as a demixing agent, a specific class of cationic surfactant which is a quaternary nitrogen-containing ether substituted alkoxylated alkyl glucoside. The aqueous and oily phases are mixed temporarily at the time of use and rapidly demixed. The demixing agent, being water-soluble, is preferably added in the aqueous phase of the composition. The reference does not teach or suggest the Applicants' film formers or their use as demixing agents in such a dual phase composition. The Examiner relies on the '095 reference for that disclosure in an attempt to establish *prima facie* obviousness of the instant invention.

The '095 reference

The '095 reference is concerned with the problem of formulating a conditioning composition, particularly for the hair, which does not leave hair with a greasy appearance and feel, such as provided by purely oil-based compositions, and how to formulate a useful composition incorporating cationic polymers and oils, when it is known that the cationic polymers are not efficacious when incorporated into the oils. Described in the patent is a product including two distinct and separately packaged compositions that are only mixed at the time of application; the composition being shaken to disperse the aqueous phase in the oily phase. Once mixed for use, the composition is not demixed. One of the liquid phases is an aqueous phase in which a cationic polymer is dissolved. The cationic polymer may be a vinylpyrrolidone acrylate or methacrylate copolymer. The other phase is an oily phase.

Combined teachings of the '758 and '095 references

It is the Examiner's position that one skilled in the art would be motivated to introduce the cationic compounds, e.g. a vinyl pyrrolidone-acrylamide copolymer, of the '095 reference into the dual phase composition of the '758 reference to provide a skin conditioning benefit.

When considering the teachings in the '095 reference in their entirety, the Applicants cannot agree with the reasoning of the Examiner. The aqueous phase in the reference

composition is kept separate from the oily phase until the time of use for the reason that the desirable properties of the cationic polymers will be compromised by prolonged contact with the oily phase. Specifically, at column 1, lines 46-57, of the reference, it is taught that, although it is possible to incorporate the cationic polymers in the oil phase, the effectiveness is very slight because their characteristic adherence to the skin or hair was inhibited in the oily medium. This is in contrast to the dual phase composition of the '758 reference (and the present invention) where, in use, the composition is mixed and rapidly demixed, with every use. The repeated mixing and demixing of the proposed dual phase composition would effectively subject the cationic polymer in the aqueous phase to contact with the oily phase upon mixing again and again such that the conditioning benefit would be expected quickly to become negligible. Therefore, although the Examiner alleges that one skilled in the art would be motivated to combine the teachings of the '758 and the '095 references and modify the compositions of the '758 reference to include the conditioning agents (i.e. cationic polymers) of the '095 reference to achieve the present invention, the Applicants assert that the disclosure in the '095 reference clearly teaches away from doing so. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the claimed invention. *In re Gurley*, 31 USPQ2d 1130, 1131 (CAFC 1994).

One skilled in the art of formulating two phase compositions would not have been led to combine the teachings of these references for yet another reason. The compositions of the '758 reference and the '095 reference clearly possess entirely different properties, the former compositions being dual phase compositions, including aqueous and oily phases which are mixed temporarily at the time of use and which rapidly demix, and the latter compositions which, when mixed at the time of use, form dispersions of an aqueous phase in an oily phase and which do not demix. As discussed above, with regard to the '496 and the '155 references, those of ordinary skill in the art of formulating emulsions would appreciate that formulating a stable emulsion is a formidable task and that one does not easily introduce a further ingredient into such stable emulsion without some prediction as to the behavior of that ingredient in the stable emulsion composition; that is, some indication that the further ingredient will not upset the delicate balance achieved in the stable emulsion. Similarly, those skilled in the art would appreciate that formulating a two phase composition which forms an emulsion only temporarily upon mixing and rapidly demixes cannot be any less difficult. The Examiner again is referred to the introductory paragraphs of the '758 reference in which it is discussed that a number of factors are to be considered in making a successful dual

phase product. For this additional reason, those skilled in the art would not have introduced cationic conditioning agents into the dual phase composition with a reasonable expectation that such addition would not upset the desired properties of the modified composition.

For all of the above reasons, it is considered that the Examiner has not established a *prima facie* case of obviousness of the present invention, and that independent claims 1 and 8 are patentable over the references cited. Dependent claims 2, 3; and 9 and 10, which depend respectively from the independent claims, are particularly preferred embodiments of the invention which recite preferred film formers for use in the invention. Dependent claims 5 and 12 describe further embodiments of the invention which specify the range of the film former. Dependent claim 7 recites a preferred ratio of the oil to aqueous phases. Dependent claim 13 calls for a preferred combination of oils in the oily phase of the composition.

It is respectfully submitted that the rejection of the claims under §103(a) in view of the combined teachings of the '758 and '095 references also should be withdrawn.

CONCLUSION

One skilled in the art, seeking to formulate a dual phase cosmetic composition, comprising an oily phase and an aqueous phase, and a novel demixing agent, which composition emulsifies rapidly and uniformly upon vigorous shaking and demulsifies completely upon resting, would not have been led by the combined teachings in the references to arrive at the present invention.

The '496 reference discloses a two phase cleansing composition, comprising an aqueous phase and an oily phase, which is mixed and rapidly demixed with each use; however, the reference does not disclose or suggest the use of a film former as a demixing agent. The '155 reference describes a product including two miscible aqueous compositions; one being a color composition and the other a gel composition. The reference teaches using, in the color composition, a film former as a dispersing/suspending (i.e. stabilizing) agent for a substantial amount of pigment, and to keep the pigment from bleeding into the gel phase. One skilled in the art would not be motivated to introduce the film former of the '155 reference into the dual phase composition of the '496 reference, since, the '155 reference teaches that this would be indicated only to disperse/suspend a substantial amount of pigment in an aqueous

phase, and there is no suggestion in the references of any advantage to introducing a substantial amount of a colorant to the cleansing composition of the '496 patent. Moreover, the addition of a further stabilizing agent in the form of a film former would be expected to interfere with the demixing capability of the two phase composition.

The '758 reference describes a two phase cleansing composition, comprising an aqueous phase and an oily phase, which is mixed and rapidly demixed with each use; however, the reference does not disclose or suggest the use of a film former as a demixing agent. The '095 reference is concerned with a conditioning product comprising two distinct and separately packaged compositions which are combined only at the time of use, and never demixed. One composition is an aqueous phase containing cationic conditioning agents, which may be film formers. The other composition is an oily composition. As the '095 reference teaches the separation of the cationic conditioning agents from the oily phase until the time of use, so as to retain the efficacy of the cationic polymers as conditioning agents, one skilled in the art would not have been motivated to introduce the film forming agents of the '095 reference into the dual phase composition of the '758 reference. One of ordinary skill in the art would predict that the repeated mixing and demixing of the proposed dual phase composition would effectively subject the cationic polymer in the aqueous phase to repeated contact with the oily phase such that the conditioning benefit imparted to the composition by the cationic polymer would quickly become negligible.

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and the issuance of a Notice of Allowance is respectfully requested.

A petition and fee for extension of time for three months is being submitted concurrently with this response. Also being submitted at this time is a Notice of Appeal with the requisite fee.

Respectfully submitted,

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Cynthia R. Miller, Esq., Reg. No. 34,678
The Estee Lauder Companies Inc.
155 Pinelawn Road, Suite 345 South
Melville, N.Y. 11747
Tel. (631) 414-6068